510(k) Summary

JUN 24 2008

SUBMITTER:

Animas Corporation
200 Lawrence Drive
West Chester, PA 19380

Contact: Amy Smith; Director, Regulatory Affairs & Change Management

DEVICE NAME:

Symphony Glucose Management System

COMMON OR USUAL NAME:

Insulin infusion pump and glucose test system

DEVICE CLASSIFICATION:

Class II per CFR 21 §880.5725, Infusion Pump, product code LZG
Class II per CFR 21 §862.1345, Glucose Test System, product code NBW

Devices used with the Glucose Test System are classified as follows:

- Class I, OneTouch® Ultra Control Solution, per 21 CFR § 862.1660.
- Class I (exempt) OneTouch® Lancing Device with OneTouch® AST ClearCap™ and OneTouch® UltraSoft® Sterile Lancets per 21 CFR § 878.4800
- Class II, One®Touch Ultra Test Strips, per 21 CFR § 862.1345

PREDICATE DEVICES:

Animas® IR 1250 insulin pump (K042873)

OneTouch® UltraSmart® Blood Glucose Monitoring System (K021819, K043197)

OneTouch® Ultra®2 Blood Glucose Monitoring System (K053529)

Medtronic MiniMed Paradigm Model 512 Insulin Pump and Paradigm Link Glucose Meter (K030531, K040603)

Insulet OmniPod iXL-II Diabetes Management System (K042792)

DEVICE DESCRIPTION:
The Symphony System combines the use of an insulin pump and a blood glucose meter for the treatment of insulin requiring diabetes. The insulin pump, Symphony Pump, operates as a stand alone device to deliver insulin through an infusion set placed subcutaneously. The blood glucose meter, Symphony Meter Remote, operates as a stand alone device to measure blood glucose concentrations. When paired through radio frequency (RF) communication the Symphony Meter Remote can be used to control bolus insulin delivery, review the status of the Symphony Pump and view and confirm selected pump alerts and warnings.

INTENDED USE:
The Symphony System is indicated for the treatment of insulin-requiring diabetes and for the quantitative measurement of glucose in fresh capillary whole blood.

The Symphony Pump is indicated for continuous subcutaneous infusion of insulin for the treatment of insulin-requiring diabetes.

The Symphony Meter Remote is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood, and as a wireless (RF) remote control to deliver insulin from the Symphony Pump. The Symphony Meter Remote is intended for use for self-testing outside the body *(in vitro* diagnostic use) by people with diabetes at home and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. The Symphony Meter Remote is specifically indicated for use on the finger, forearm or palm. It should not be used for the diagnosis of diabetes or testing of newborns.

SUBSTANTIAL EQUIVALENCE:

The Symphony System is similar to the Paradigm Model 512 Insulin Pump and Paradigm Link Glucose Meter in that both systems are comprised a pump and meter that can be operated independently as stand alone devices. The main difference between the Symphony System and the Paradigm Model 512 Insulin Pump and Paradigm Link Glucose Meter is that the communication for the Symphony System is bi-directional which allows for the display of pump information on the meter remote screen and allows for the meter remote to control bolus insulin delivery of the pump. In the Paradigm Model 512 Insulin Pump and Paradigm Link Glucose Meter the only communication is one-direction (meter to pump) for the communication of a blood glucose value.

The Symphony System is similar to the Insulet OmniPod iXL-II Diabetes Management System in that both systems allow for bi-directional RF communication. This allows pump information to be displayed on the meter remote and for the control of insulin delivery. These systems also have the same intended use. The Symphony System is different to the Insulet OmniPod iXL-II Diabetes Management System in that the pump in the Symphony System can be used as a stand alone device if the meter remote is not available or RF communication is not possible (such as on an aircraft). In the Insulet

OmniPod iXL-II Diabetes Management System the pump is a pod that contains no user interface.

The Symphony Pump is most similar to the Animas IR 1250. The Symphony Pump is not a new design, but a modification to the Animas IR1250 insulin pump. The differences between the Symphony Pump and the Animas IR1250 insulin pump are the color display, increased number of insulin calculator settings, RF capability, size, weight and the additional alarms associated with RF capability.

The Symphony Meter Remote is a modification to the OneTouch UltraSmart Blood Glucose Monitoring System (K021819). The modifications included both hardware and software changes to implement the requirements for its intended use as a remote control for the Symphony insulin pump. It is also similar to the OneTouch® Ultra®2 Blood Glucose Monitoring System (K053529). A food database and insulin calculator feature have been added to the meter. Like the OneTouch UltraSmart and OneTouch Ultra 2 Blood Glucose monitoring systems, the Symphony Meter Remote uses the OneTouch Ultra Test Strips and Control Solution. Both the subject and the predicate devices store blood glucose results and allow for download to a PC for use with a data management system.

RESULTS OF PERFORMANCE EVALUATION:

Performance evaluations, both bench and clinical, of the Symphony System were completed and did not raise any new issues of safety and efficacy.

CONCLUSION:

The Symphony Glucose Management System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2008

Ms. Amy Smith
Director, Regulatory Affairs & Change Management
Animas Corporation
200 Lawrence Drive
West Chester, Pennsylvania 19380

Re: K080639
Trade/Device Name: Symphony Glucose management System
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: June 3, 2008
Received: June 4, 2008

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

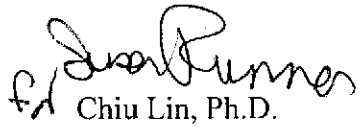
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: Symphony Glucose Management System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080639